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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/576,097	05/22/2000	Laman Alani	6499.US.O2	3170

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ROBERT DEBERARDINE
ABBOTT LABORATORIES
100 ABBOTT PARK ROAD
DEPT. 377/AP6A
ABBOTT PARK, IL 60064-6008

EXAMINER	
LUKTON, DAVID	
ART UNIT	**PAPER NUMBER**
1654	

DATE MAILED: 07/06/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/576,097	ALANI ET AL.	
	Examiner	Art Unit	
	David Lukton	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 May 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-11 and 14-21* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3-11 and 14-21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Pursuant to the directives of the response filed 5/6/05 claims 1, 4, 8-11, 14, 15, 17, 18, 20 have been amended. Claims 1, 3-11, 14-21 remain pending.

The claim listing filed 5/6/05 is not correct. The listing shows claims 12 and 13 as pending. However, these claims were cancelled pursuant to the directives of the response filed 5/21/02. Claims 1, 3-11, 14-21 are regarded as pending.

Applicants' arguments filed 5/6/05 have been considered and found persuasive in part. The rejection of claims 1, 3-11, 14-21 under 35 U.S.C. 112, first paragraph is withdrawn.

✧

Claims 1, 3-11, 14-21 are rejected under 35 U.S.C. §112 second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

- Most of the claims recite the term "about" in reference to a range. For example, claim 1, part (a) recites the following: "about 1% to about 50%". The presence of the term "about" renders the claims indefinite as to the upper and lower limits. In response to this ground of rejection, applicants have argued that *Ex parte Eastwood* confers "immunity" from §112 second paragraph rejections in cases where the claim recites the term "about" in reference to a range. However, the panel of judges in *Amgen, Inc. v. Chugai Pharmaceutical Co.,* (927 F.2d 1200, 18 USPQ2d 1016 (Fed. Cir. 1991)) held that claims reciting "at least about" were invalid for indefiniteness. Accordingly, there is no universal view that the "immunity" implied by applicants does or should exist. Consider, for example, claim 1. Where exactly would applicants draw the line between a composition that falls within the scope of the claims, and one which does not? If the ritonavir and the second HIV inhibitor together constitute 0.5% of the total composition, would this be encompassed? Which controls, the "about" qualifier, or the requirement that the composition contain at least 1% of the inhibitor?

- As indicated previously, claim 1 recites weight percentages. At the lower end, the claim permits the ritonavir, solvent and water to constitute only 42.4% of the total mixture. For this embodiment, the claim mandates the presence of at least one other component that constitutes 57.6% of the total composition. Thus, the claim mandates that more than half of the claimed composition consists of an unidentified compound, or an unidentified mixture of compounds. In response, applicants have argued that the term "mystery component" does not appear in the claims. Applicants are quite correct about this, but that observation does not contribute to the analysis in any fundamental way. Next, applicants have suggested that the examiner might be unfamiliar with the term "comprising". Applicants are advised that the examiner is well versed in the meaning of this term. The examiner never meant to suggest that a skilled artisan considering the claims would come to believe that the claimed invention violates some fundamental laws of chemistry or physics, or that the the claimed invention violates basic principles of mathematics, or even that the failure to identify all components is illogical. Certainly, the skilled scientist or patent prosecution specialist would recognize that something else must be present when the ritonavir, solvent and water constitute only 42% of the total mixture. If a skilled chemist were presented with a mixture, any mixture, falling within the scope of the claimed invention, he would be able (at least in principle) to analyze it and determine all of its contents such that 100% of the composition is accounted for. But the fact remains that there is a genus of embodiments in which more than half of the composition is unaccounted for. The claims remain indefinite. As a further step in the dialog, it is suggested that applicants come up with 3 or 4 examples of composition in which the ritonavir, solvent and water constitute only 42% of the total, and the remaining 58% is accounted for in applicants' explanation. If applicants are not able to come up with even one example of a fully defined composition in which ritonavir, solvent and water constitute only 42% of the total, it is difficult to make the argument that the skilled artisan could figure out which compositions are encompassed, and which are not. Applicants have also argued that it is "quite obvious" that all of the components of the composition must add up to 100%. However, where there is a contradiction between what is stated in the claims, and what is argued in a response, it is appropriate to give greater weight to what is in the claims. If it is really true that applicants believe that all of the components of the composition must add up to 100%, applicants should feel no reluctance in demonstrating their conviction by amending the claims in a manner consistent therewith.

- In claim 7, the phrase "the solution" lacks antecedent basis.

- In claim 9, the term "the solvent" lacks antecedent basis. It is acknowledged that the phrase "pharmaceutically acceptable organic solvent" is present in part (b) of

claim 1. However, water does not meet any of the criteria of an "organic solvent" (claim 9 requires that the solvent contain water). And even if applicants were to delete the term "organic" from part (b) of claim 1, claim 9 would still not be properly subgeneric to claim 1. The reason is that claim 1 gives no indication that the solvent can contain water. It is of course true that the overall pharmaceutical composition can contain water, but the solvent of part (b), whether organic or otherwise, does not contain water. The same issues apply in the case of claim 8.

- In claim 16, the phrase "the solution" lacks antecedent basis.

- In claim 17, line 5, the following is recited: "3-methyI butanoyl)-". This appears to contain a typographical error.

- In claim 18, the phrase "the solution" lacks antecedent basis.

- In claim 21, the phrase "the solution" lacks antecedent basis.

✦

The following is a quotation of 35 USC. §103 which forms the basis for all obviousness rejections set forth in the Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Subject matter developed by another person, which qualifies as prior art only under subsection (f) and (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made, absent any evidence to the contrary. Applicant is advised of the

obligation under 37 C.F.R. 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103.

Claims 1, 3-11, 14-21 are rejected under 35 U.S.C. §103 as being unpatentable over Sham (WO 97/21685) in view of Yamamoto (USP 5,264,223) or Yamamoto (USP 5,756,123).

As indicated previously, Sham discloses (beginning on page 126, last paragraph) the invention substantially as claimed, except for the presence of water. Yamamoto ('223) discloses capsules in which the water content is about 5%; Yamamoto ('123) discloses capsules in which the water content is in the range of 1-6%. Yamamoto does not disclose the claimed compositions. The claims encompass the possibility of a completely anhydrous composition being contained within a capsule that contains a small quantity of water such that the overall composition, including the capsule, contains 0.4% to 3.5% water. It is to this embodiment that the rejection is targeted.

In response to the foregoing, applicants have argued the following:

"Obviously, claim 1 is directed to a composition containing, among other things, water in an amount of from about 0.4 to about 3.5 weight % of the composition. This composition is then encapsulated. There is no possibility of the composition being anhydrous, it requires water in an amount of from about 0.4 to about 3.5 weight % of the composition. This composition containing water is then encapsulated. Therefore, the embodiment that Examiner has targeted with a rejection does not exist."

Thus, applicants are arguing that somewhere in the independent claims, there is a statement that the "composition" excludes gelatin, or at least that a skilled drug formulation specialist would somehow believe that if one takes a composition and combines it with gelatin, the

resulting composition loses its property of being a composition. Clearly, there is ~~clearly~~ no recitation in the claims that the composition must exclude gelatin. Nor is there any reason why a chemist or biochemist or drug formulation specialist would believe that the term "composition" is such as to exclude mixtures of compounds which contain gelatin. In short, applicants are attempting to argue a limitation which is not present in the claims.

Next, applicants have offered the general proposition that when an examiner imposes a §103 rejection over two references, he must provide motivation to combine references. Applicants have gone on to cite court cases that support this assertion, but applicants have made no attempt to argue, with any specificity, what motivation is lacking. Surely, applicants do not believe that they are the first to discover gelatin capsules. Nor can applicants argue that use of gelatin capsules would be somehow undesirable, or that the prior art "teaches away" from the use of gelatin capsules. Nevertheless, with regard to Yamamoto specifically ('123 and '223), applicants are correct that the examiner must provide motivation for the drug formulation specialist of ordinary skill to use the capsules of Yamamoto. With regard to this issue, Yamamoto does indeed provide assertions regarding the advantages of his capsule over other capsules. See, for example, col 6, line 33+ of '123, and col 6, line 50+ of '223. Thus, the drug formulation specialist of ordinary skill would have been motivated to use the capsules of Yamamoto in order to realize the advantages recited therein.

The rejection is maintained.

✦

Claims 1, 3-11, 14-21 are rejected under 35 U.S.C. §103 as being unpatentable over Al Razzak (USP 5,948,436).

As indicated previously, Al Razzak teaches the elements of the claimed invention. Applicants have argued that the compositions of Al Razzak do not contain fatty acids. It may be true that the disclosed compositions do not contain free fatty acids, but they contain fatty acids nontheless, as indicated in col 6, line 50+.

In response to the foregoing, applicants have argued that the skilled biologist or chemist would never interpret the term "fatty acids" to be generic and encompass the possibility of fatty acid esters. The examiner would readily agree that the skilled organic chemist or lipid chemist completely understands the difference between an acid and an ester. And to go a step further, even the average undergraduate student who has taken a semester of introductory organic chemistry understands the difference between an acid and an ester. But the question of how a skilled scientist might interpret the meaning of the term "fatty acid" is less clear. If a professional organic chemist or lipid chemist were informed that each of the semantic terms he was using were going to be place "under a microscope" and analyzed, he would not make the mistake of referring to a fatty acid ester as a fatty acid, or *vice versa*. But consider the case of a membrane biologist, for example. While the membrane biologist understands the difference between an ester and an acid, he might, at the same time, regard the term "fatty acid" as being generic to compounds that are fatty acids *per se*, and those that are esterified. This is not so much a question of ignorance as it is of semantic laxity. Consider another example. Quite often,

when a chemist or biologist uses the term "protein", he is really referring to glycoprotein. In such a situation, it is rarely the case that the chemist or biologist fails to recognize the structural distinction between the two; instead, the chemist or biologist is simply using the term "protein" generically. A similar analysis applies when the protein is phosphorylated or sulfated. Another example pertains to the term "amino acid". There may be agreement as to what the rigorous definition of this term is (at least in the case of genetically encoded amino acids), and yet when commonly used, the term at issue can mean an amino acid *per se*, or an amino acid minus the elements of water or an amino acid minus a hydrogen atom or an amino acid minus hydroxide, or a salt of an amino acid. And the term at issue can also encompass amino acids that have been phosphorylated or sulfated or esterified.

Applicants' position appears to be that when a scientific term is taken out of context, there is always agreement among skilled scientists as to exactly what is intended. It is on this point that applicants and examiner disagree. If it is really the case that applicants intend for the term "fatty acid" to mean *free fatty acid*, applicants should feel no reluctance in amending the claims to recite the latter term. As matters currently stand, however, the rejection is maintained.

✦

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a). The practice of automatically extending the shortened statutory period an additional month upon filing of a timely first response to a final rejection has been discontinued by the Office. See 1021 TMOG 35.

A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED AND ANY EXTENSION FEE PURSUANT TO 37 CFR 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Lukton whose telephone number is 571-272-0952. The examiner can normally be reached Monday-Friday from 9:30 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell, can be reached at (571)272-0974. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.

DAVID LUKTON
PATENT EXAMINER
GROUP 1800